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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/426,931	10/22/1999	WOLFGANG-REINHOLD KNAPPE	BMID9826US	2537

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RICHARD T KNAUER  
ROCHE DIAGNOSTICS CORPORATION  
9115 HAGUE ROAD BLDG D  
PO BOX 50457  
INDIANAPOLIS, IN 462500457

EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/426,931	<b>Applicant(s)</b> KNAPPE, WOLFGANG-REINHOL	
	<b>Examiner</b> LaToya I. Cross	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2004.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 41-48 and 56-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 56, 61 and 62 is/are allowed.
- 6) ☒ Claim(s) 41-43, 46-48 and 57-60 is/are rejected.
- 7) ☒ Claim(s) 44 and 45 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This Office Action is in response to Applicants' amendments filed on 5/12/04. Claims 41-48 and 56-62 are pending. Claims 61 and 62 have been newly added.

#### *Terminal Disclaimer*

The terminal disclaimer filed on 05/12/04 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,537,496 has been reviewed and is NOT accepted.

- a. The person who signed the terminal disclaimer is not recognized as an officer of the assignee, and he/she has not been established as being authorized to act on behalf of the assignee. See MPEP § 324.

An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c).

#### *Claim Objections*

Claims 44 and 45 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 61 and 62. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

New claims 61 and 62 are a duplicate of claims 44 and 45. Since Applicants amended claims 44 and 45 to be in independent form as claims 61 and 62, then the claims contain all the same limitations and are duplicates. It is suggested that Applicants cancel claims 44 and 45.

***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 41-43, 46-48 and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al in view of Dreyfus.

Good et al '224 teach a diagnostic test strip for determining the presence of a specified analyte in a fluid sample. The test strip has a test membrane sandwiched between two layers. The test membrane has a sample-receiving zone containing a buffer and a fatty acid sarcosinate. The sample-receiving zone (21) is a pad made of non-woven fibrous material, for example paper or polyurethane polymer material. The sample is absorbed by the pad, solubilizes the buffer and fatty acid sarcosinate and migrates to an adjacent reagent zone (22) containing reagent chemicals in fibrous matrix. The sarcosinate is present in a concentration of about 1.0 % by weight. Good et al '224 also disclose that the sample-receiving zone is made by imbibing a solution containing a suitable buffer and fatty acid sarcosinate into a sheet to provide the appropriate concentration. See col. 4, lines 8-16 and col. 5, lines 8-27. With respect to the test fields recited in claims 41-43 and 46-48, Good et al '224 teach test layers comprising a test zone, control zone, reagent zone and sample receiving zone. The sample receiving zone is a fibrous pad containing the fatty acid sarcosinate wetting material. The sample receiving zone overlays the other zones (reagent, test and control), as recited in claim 41. Figure 3 shows the fields overlaying one another, as recited in claim 46. With respect to claim 47, Good et al teaches an inert plastic layer (31) having an aperture to allow sample application. With respect to claim 57, Good et al teach a further embodiment where the plastic encasing is removable.

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Thus, the overlay (sample receiving zone) may be displaced from the detection zone and the remainder of the test strip.

Although Good et al '224 teach fatty acid sarcosinates as wetting agents, Good et al '224 fail to specifically teach the use of oleoyl sarcosinate as the wetting agent.

Dreyfus '987 teaches fatty acid sarcosine as good wetting agents. At col. 2, lines 20-30, Dreyfus teaches higher fatty acid radicals, such as those containing more than 8 carbon atoms are suitable. Dreyfus specifically teaches the oleic acid radical as an example where valuable results may be obtained. The fatty acid sarcosines are particularly used in wet treating textile materials such as fabric-like material.

It would have been obvious to one of ordinary skill in the art to use the oleoyl sarcosine wetting agents taught by Dreyfus in the test strips of Good to provide better wetting properties to the fibrous pads and allow sample to be up taken more efficiently.

With respect to the claims requiring specific weights and thickness of the fibrous material, such would be dependent on the type of sample and amount of sample needed to conduct the analytical test. The skilled artisan would have been able to determine a suitable weight and thickness for the particular sample being collected.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious within the meaning of 35 USC 103 in view of the teachings of Good et al '224 and Dreyfus '987.

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*,

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686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 41-43, 57-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,537,496.

Although the conflicting claims are not identical, they are not patentably distinct from each other because, the patented claims recite an N-acyl-N-alkyl-glycinate as the wetting agent.

The disclosure of the patent specifically defines N-oleoyl sarcosinate as the preferred glycinate wetting agent. Thus, the claims of the patent are not distinguishable from the claims of the instant invention.

#### ***Allowable Subject Matter***

5. Claims 56, 61 and 62 are allowed.

The prior art of record fails to teach two overlay elements, as recited in claims 44 and 61, wherein the overlay elements face one another and whose parts are displaceable from the test strip. Further, with respect to claim 56, the prior art of record fails to teach a spreading material overlay larger than a test field and support on two sides of the test field by way of a spacer.

*Response to Arguments*

7. Applicant's arguments filed May 12, 2004 have been fully considered but they are not persuasive. In response to the rejection over Good et al in view of Dreyfus, Applicants argue that Good et al fail to teach that the overlay is in direct contact with the detection layers. Applicants state that Good et al teach that a reagent zone is present in between the layer having the fatty acid sarcosinate wetting agent and the test results layer. In response, the Examiner would like to point out that the reagent zone/layer (62) could be equivalent to Applicants' claimed detection layer, since as in Applicants' device, the reagent layer (62) of Good et al contains the necessary reagents to perform the analysis. Thus, like Applicants', Good et al teach that the layer having the wetting agent contacts the layer having the reagents needed to analyze the sample.

Applicants further argue, with respect to claims 57-60 that Good et al fail to teach that the overlay is capable of moving freely with respect to the test fields. This limitation involves how the overlay material operates, which is not sufficient to impart patentability to the claims. MPEP 2114 states that apparatus claims should be structurally distinguished over the prior art should define what the "device is and not what a device does". It is suggested that Applicants distinguish the device over Good et al, with respect to the free movement of the overlay layer, by incorporating language similar to that in the full paragraph on page 19 of the specification, where it states that the spreading layer is attached to the test strip on both sides of the test field using spacers provided with adhesion layers. This will allow claim 57 to be structurally different, as opposed to functionally different, from the device of Good et al.

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8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ARLEN SODERQUIST  
PRIMARY EXAMINER

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